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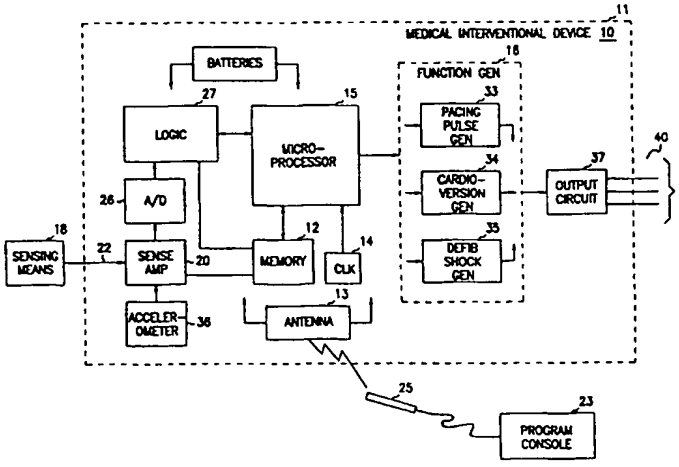
(54) Title: METHOD AND APPARATUS FOR DUAL CHAMBER BI-VENTRICULAR PACING AND DEFIBRILLATION



(57) Abstract

Device and method are disclosed in which leads with pacing and defibrillating electrodes are implanted into both the right and left ventricles of a patient's heart to enable simultaneous pacing of both ventricles to reduce the width of the QRS complex of the patient's cardiac activity to a more normal duration, and, when appropriate, to apply electrical shock waveforms to both ventricles simultaneously for lower energy defibrillation of the ventricles. In applying the defibrillation therapy, the defibrillating electrode in the left ventricle may be used as the anode and the defibrillating electrode in the right ventricle may be used as the cathode, or both ventricular defibrillating electrodes may be the anode and the metal case in which the shock waveform generator is implanted may be the cathode. Implanting a lead with pacing and defibrillating electrodes in the right atrium enables selective pacing and defibrillation of the atria, in which atrial fibrillation is treated by applying the shock waveform across the right atrial and left ventricular defibrillation electrodes.

METHOD AND APPARATUS FOR DUAL CHAMBER BI-VENTRICULAR PACING AND DEFIBRILLATION

Background of the Invention

The present invention relates generally to implantable medical devices for treating cardiac dysrhythmias, and more particularly to a multi-mode device which is adapted to provide bi-ventricular therapy to the patient's heart in response to sensing applicable dysrhythmias.

Progress in medicine is based largely on progress in the technology of devices and apparatus for administering therapy. For example, significant advances in design techniques that have resulting in continuing reductions in the size of implantable defibrillators, including size of the function generator itself as well as in the heart leads associated therewith, have led to a capability to implant defibrillators at considerably lower risk to patients. During the first few years following the advent of implantable defibrillators, implant procedures required general anesthesia and thoracotomy, and the patient was faced with all of the risks associated with opening the chest cavity. The morality rate of the procedure tended to limit widespread use of the device.

In recent years, with lower defibrillation thresholds (DFTs) and reduction in high voltage capacitor and battery sizes, smaller and more easily implantable devices have been developed, which have allowed this operation to be performed today under only local anesthesia. Smaller diameter and more easily inserted transvenous lead systems have overcome the need for a thoracotomy, and mortality associated with the procedure has been concomitantly reduced to less than one percent. The cosmetic aspects of such an implantation have also improved, with device size and weight allowing it to be implanted in the pectoral region that had previously been reserved for devices capable of only pacing functions, rather than the lower abdomen.

Nevertheless, at least two issues remain to be resolved with respect to present-day implantable defibrillators. For one thing, despite size reduction owing to the aforementioned advances in technology, the devices are still relatively large. At present, the limitations on size reduction are primarily attributable to the magnitude of energy required to achieve successful

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In practice, then, because a relatively lower energy field is present at some regions that may be critical to defibrillation, the energy gradient sufficient to achieve successful defibrillation by application of the shock waveform mandates an adequate energy level in those regions and, by extension, a considerably higher electric field density in the normally higher energy field locations as well. The result is a further skewing of the inequality or inhomogeneity of the electric field distribution in the strategically important regions.

In one of its aspects, the present invention provides improvements in lead and electrode placements to assist in developing an equal, homogeneous field distribution during application of a defibrillation shock to the heart.

Another problem encountered with present day defibrillators, however, is that despite their capability to provide adequate therapy for sudden electrical instabilities of the cardiac function, they are not similarly capable of providing therapy for an underlying hemodynamically-compromised ventricular function. This means that the patient may suffer an ongoing deficiency in cardiac output, for example, even though the device is effective in correcting isolated events of fibrillation or pacing dysrhythmias.

Clinical investigation performed on patients who suffer from heart failure (i.e., inability of the heart to pump the required amount of blood) indicates that for a certain subset of these patients simultaneous stimulation of the left and right ventricles may be advantageous. In the cardiac cycle, a P wave of the subject's electrocardiogram (ECG) is produced by a depolarization of the atrial fibers just before they contract, and, when the cardiac impulse reaches the ventricular fibers to stimulate them into depolarization, a QRS complex is produced just before contraction of the ventricular walls. This is followed by a T wave which is indicative of the electrical activity occurring upon repolarization of the ventricular fibers. Simultaneous stimulation of the left and right ventricle would be beneficial therapy to patients whose ECG displays a marked desynchronization in contraction of the two ventricular chambers. In such cases, it is observed that after a right ventricular stimulation, considerable time may elapse for the cardiac impulse to travel from the apex of the right ventricle

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According to the invention, a second ventricular lead is placed in the left ventricle by needle puncture of the arteria subclavia (left subclavian artery) or the brachiocephalic artery, and advancement into the left ventricular chamber through the aortic valve. To avoid interference with the mechanical function of the aortic valve during retrograde passage of this lead into the left ventricle, or thereafter while in place, the lead should be of relatively smaller diameter than traditional ventricular leads (e.g., in a range of 6 to 7 French, or less). Also, its outer surface should be composed of electrically insulative material of very low thrombogenicity (e.g., high performance silicone or polyurethane). Local formation of a thrombus that could embolize and travel to the brain through the aortic valve is additionally avoided by use of platelet (thrombocyte) inhibitors (e.g., preferably ticlopidine, but alternatively or additionally aspirin, GPIIb/IIIa blockers or other inhibitors of the fibrinogen receptor), and by plasmatic coagulation inhibitors (e.g., heparin and hirudin). Such inhibitors are preferably administered for a duration of about one to three months following the surgical procedure. This time period should be adequate to allow a build-up of protective connective tissue around the electrode and also to prevent adhesion of the lead body in the vicinity of the aortic valve.

The left ventricular lead is otherwise of similar construction to the right ventricular lead, and enables pacing stimulation of the left ventricle simultaneously with pacing stimulation of the right ventricle, with resulting improvement in hemodynamics, in large measure by virtue of more organized contraction and avoidance of mitral regurgitation. It is also possible, albeit difficult, to place a lead with a pacing electrode in the left atrium. This is achievable, preferably, by inserting the lead into the left atrium by access from the adjacent distal coronary sinus, or, alternatively, by access through the arterial septum wall from the right atrium. This enables simultaneous pacing of the right and left ventricles according to the preset A-V delay, in a DDD mode, plus the capability for bi-ventricular defibrillation.

Most importantly, placement of a defibrillation coil on a lead in the left ventricle allows a considerable reduction of the energy requirement necessary to achieve a successful shock (i.e., termination of ventricular fibrillation, and return to sinus rhythm), with a threshold (DFT) that may be as low as only 2 to 3 joules

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The lead adapted for insertion into the left ventricle includes an insulative sheath composed of a material of low thrombogenicity, such as a material selected from a group which includes high performance silicone and polyurethane. Also, the insulative sheath is coated at least in part with a biodegradable material to inhibit thrombus formation on the respective lead. The biodegradable material coating may be impregnated with at least one platelet inhibitor (preferably, iloprost) for timed release during disintegration of the coating. The coating may additionally or alternatively be impregnated with a plasmatic coagulation inhibitor such as heparin or hirudin for time release.

The function generator includes a shock generator adapted for defibrillating the patient's heart by generating higher voltage electrical shock waveforms. Each of the leads includes a defibrillation coil coupled to the shock generator and located on its lead to be positioned within a respective ventricle to apply an electrical shock waveform to establish a substantially homogeneous electric field of sufficient electrical energy through the ventricles for defibrillation thereof. The defibrillation coils constitute defibrillation poles, and when energized simultaneously the defibrillation coil in the left ventricle is the anode and the defibrillation coil in the right ventricle is the cathode. Alternatively, the ventricular defibrillation coils constitute a single defibrillation pole and are energized simultaneously as an anode, and the metal case within which the function generator is housed constitutes a second defibrillation pole which is energized together with the defibrillation coils as a cathode. An atrial pacing lead includes a pacing electrode coupled to the pulse generator, and a defibrillation coil adapted to be positioned within the right atrium and coupled to the shock generator for defibrillation of the atria.

A variation of the invention is implemented in an implantable pacemaker that includes a pulse generator, a right ventricular pacing lead with an electrode coupled to the pulse generator for positioning in the right ventricle to deliver stimulating pacing pulses from the generator thereto, a left ventricular pacing lead with an electrode coupled to the pulse generator for positioning in the left ventricle to deliver stimulating pacing pulses from the generator thereto, and means for applying selected ones of the stimulating pacing pulses to the right and left ventricular pacing leads for stimulating the ventricles simultaneously.

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Another aspect of the invention resides in a method for providing therapy to a patient from a medical interventional device to treat cardiac dysrhythmias, wherein the device performs a plurality of functions corresponding to different levels of therapy for treatment of sensed dysrhythmias. The device responds to each different type of sensed dysrhythmia to generate an electrical waveform therapy among a variety of therapies appropriate to terminate the respective sensed dysrhythmia, including at least electrical pulse and shock waveform therapies therefor. The method includes implanting an electrical lead with an electrode to deliver at least one of the pulse and shock waveform therapies in each of the right and left ventricles, and electrically connecting each lead to the device to enable its electrode to receive at least one of the therapies.

In the method, prior to implanting the lead, at least a portion of the lead to be implanted in the left ventricle is coated with a biodegradable carrier impregnated with a thrombus inhibitor adapted to be time-released into blood in the locality of the portion of the lead in the left ventricle during disintegration of the carrier, to avoid embolization of a thrombus thereat. The method includes selecting the biodegradable carrier to degrade harmlessly in the blood with negligible systemic impact, and selecting at least one of ticlopidine and aspirin as concomitant oral therapy and intravenous or subcutaneous administration of heparin and hirudin, as the thrombus inhibitor. Also, at least one physical parameter of the biodegradable carrier is selected to fix complete disintegration of the carrier within a period of from about one month to about three months from the time of implanting the lead, for time-release of the thrombus inhibitor over the period. The electrical lead is placed in the left ventricle by puncturing one of the subclavian and brachiocephalic arteries, inserting the lead through the puncture, and advancing the lead through the aortic valve into the left ventricle until the electrode is properly located therein. Each ventricular lead includes both a pacing electrode at the distal end of the lead and defibrillating electrode proximal of the pacing electrode, and advancement of each lead into the respective ventricle includes placing the pacing electrode in proximity to excitable cardiac tissue of the ventricle.

In the method, the right and left ventricles are paced simultaneously, whereby to reduce the duration of the QRS complex of the patient's

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used. Device 10 includes a function generator 16 for providing a plurality of functions corresponding to different levels of therapy for treatment of dysrhythmias. These may include generating relatively low energy pulse waveforms for pacing therapy including anti-bradycardia and anti-tachycardia pacing, moderate energy shock waveforms for cardioversion therapy, and relatively higher energy shock waveforms for defibrillation therapy. An output circuit of function generator 16 supplies the designated therapy to a set of leads and electrodes for delivering it to designated chambers of the heart. The output circuit may include capacitors and high voltage switches for producing high energy defibrillating shocks, and the electrodes may include the biocompatible metal housing (i.e., the case, or "can") 11 of device 10 as an active electrode, if desired for a particular type of therapy.

Function generator 16 performs its therapy-generating and delivery functions under the control of a microprocessor 15 containing arithmetic, logic, and control circuitry in conjunction with peripheral circuits or subsystems such as memory 12, clock 14, etc., as a central processing unit (CPU) for the device. The microprocessor responds to instructions to perform high speed, real-time functions for controlling the operation of the function generator. The memory units may be written to and read from, by telemetry between device 10 and a program console 23 through a wand 25 via antenna 13, and with related software, so that the microprocessor performs desired functions. These functions may then be varied by means of the programming console, or programmer 23, by the device manufacturer or the patient's attending physician.

Sensing means 18 within or outside the device housing 11 detects any of various physiologic parameters indicative of the patient's cardiac functions and physical status, to sense dysrhythmias and initiate appropriate response mechanisms from the device. Sensed parameters may include the patient's electrogram (ECG), heart rate and/or rhythm, status of rest, exercise or activity of the patient (e.g., using an accelerometer 36 within the case 11, as here, or in its own separate housing), etc., the latter enabling the device 10 to provide a rate adaptive response, as well as other dysrhythmia correction therapies. The sensing means also includes conventional sensors of physiological signals for detecting congestive heart failure, for example.

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Some therapeutic output waveforms produced by the microprocessor-based function generator 16 may be used to treat more than one rhythm disorder. For example, a burst of pulses may be used for therapy to terminate a tachycardia, or may be one among a hierarchy of therapy responses selectively delivered to perform cardioversion. The waveform representing the appropriate therapy to treat the sensed dysrhythmia within the designed capabilities of device 10, i.e., pulses, pulse bursts or trains, low energy or high energy shocks, is applied through output circuitry 37 to the applicable heart lead(s) 40 for delivery to preselected locations within the heart. These and other leads may also convey sensed signals from electrodes in or on the heart or at other appropriate locations of the patient's body, and may acquire the ECG morphologies, for return to the device (e.g., for application to the sense amplifier, or for storage in memory and subsequent retrieval by the programming console via telemetry).

FIG. 2 shows the header 50 of case 11 which incorporates an electrical connector block 52 including receptacles (e.g., 54, 55, 56) for receiving the heart leads 40. The distal ends of the leads are inserted by the physician into the appropriate preselected locations within the patient's heart, and are then connected to the circuitry within the function generator of the device 10 by means of the plug connectors at the proximal ends of the leads, which are inserted into the proper receptacles. It should be emphasized that the connector portion of the header shown in FIG. 2 is not intended to represent a complete connector. As pointed out above, other leads may be plugged into appropriate receptacles for delivering sense signals from the heart or elsewhere in the body, including signals indicative of ECG morphology.

The receptacles 54, 55, 56 of the connector block 52 are sized or otherwise coded to avoid or prevent acceptance of the plug-in connector of any lead other than the proper lead for electrical connection to the internal circuitry of device 10. Once the leads are in place and connected to the device various tests are performed to assure that they are properly seated, such as to detect capture and suitable threshold. Various unique aspects of the connector portion of the device will be discussed in greater detail presently.

FIGS. 3 and 4 represent a phantom partial front view of a patient 60 illustrating the position of the device case 11 implanted in the left pectoral region

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ventricle, by application of appropriate electrical signals to the proximal end of the lead via the connector block in the header of the implanted defibrillator.

The right atrial lead 63 provides pacing stimulation via electrode 64 to the right atrial chamber 65 from device 10, and also enables defibrillating shocks to be delivered to its associated coil electrode 62 in that chamber from the defibrillator section of the device to which the atrial lead is also connected at the header. These leads allow stimulation in VVI, VVI-R (by means of an activity sensor in the defibrillator), DDD, DDD-R, AAI, AAI-R, and other modes. The defibrillating shocks can be applied between the coil of the respective lead and the active can 11.

According to the invention, a left ventricular lead 72 is inserted into the left ventricle 73 by advancement into the arteria subclavia 74 which is either punctured or exposed by surgical preparation for access to the arterial system. Alternatively, the left ventricular lead may be implanted by puncture of the truncus brachiocephalicus and insertion through that puncture. Another technique is to surgically expose either the subclavian artery or the brachiocephalic artery and to apply a circular tightening suture ("tabakbeutelnaht"). This assists in tightening up the site of entry to avoid internal bleeding, which is especially important where subsequent anti-coagulation measures are employed by use of platelet inhibitors as is more fully explained below.

It is essential that the outer surface of this lead 72 be of very low thrombogenicity, such as by use of high performance silicone or polyurethane insulation, and by other techniques which will be described presently. It is also important that the lead body be of very small diameter, e.g., in a range from less than about 7 F, so as not to compromise the mechanical function of the aortic valve 80 during retrograde passage into the left ventricle 75 or during the valve's operation in the cardiac cycle.

Advanced materials and fabrication techniques have enabled reductions in size of heart lead diameters for implantable defibrillators to a range of 5 to 7 French (1.66 mm to 2.33 mm) from previous sizes that ranged from 9 to 11 French (i.e., 3.00 mm to 3.66 mm). More recent developments in coated wire techniques have made it possible to produce lead diameters in an even smaller

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inhibitors over a limited period of time (e.g., from one to three months following the operation) can serve to prevent the incidence of local thrombus formation until protective connective tissue builds up around the electrode. Animal and human studies have demonstrated that a very thin protective layer of connective tissue can be formed in as little as three to six weeks. Monocytes, which are present in the blood, deposit on the surface and convert into fibroblast, which builds this connective tissue. It is essential that the process should take place for a sufficient period of buildup of the connective tissue to shield the foreign body and later leave it as a neutral foreign body, to prevent thrombus formation. This may be assisted as well by application to the lead surface of inhibitors of plasmatic coagulation, such as heparin and hirudin, and by inhibitors of platelet aggregation, such as aspirin, membrane or surface receptor GP (glycoprotein) IIb/IIIa blockers (i.e., platelet inhibitors that act on the GP IIb/IIIa receptor), or other inhibitors of the fibrinogen binding receptor.

These inhibitors may be applied by incorporating them into a biodegradable carrier which is used to coat the surfaces of interest, as disclosed in co-pending U.S. patent application Serial No. 08/798,333 of E. Alt et al, the specification of which is incorporated by reference herein. According to that invention, the carrier itself is a substance or composition that undergoes continuous degradation or disintegration within the body to self-cleanse the coated surface as well as to release thrombus inhibitors incorporated in the coating. The carrier degrades slowly through hydrolytic, enzymatic or other degenerative processes. Blood components including albumin, adhesive proteins, and thrombocytes are unable to adhere to the protected surface because of the continuous cleansing action along the entire surface. Additionally, the added inhibitors undergo slow release with the controlled degradation of the carrier.

The coating carrier is a synthetic or naturally occurring biodegradable polymer such as aliphatic and hydroxy polymers of lactic acid, glycolic acid, mixed polymers and blends, polyhydroxybutyrates and polyhydroxy-valeriates and corresponding blends, or polydioxanon, modified starch, gelatine, modified cellulose, caprolactaine polymers, polyacrylic acid, polymethacrylic acid or derivatives thereof, which will not alter the structure or function of the material

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valve, to prevent adhesion of the lead to the leaflets of the valve. The amount and dosage of the drug(s) incorporated into and released from the biodegradable carrier may be prescribed to suppress the thrombus formation process locally without otherwise affecting normal systemic functions.

With both the left ventricular lead 72 and the right ventricular lead 66 in place, pacing stimulation from the implanted device 10 may be applied simultaneously to both pacing electrodes 73 and 67 of the respective ventricular chambers. By synchronizing the mechanical contraction from the apex of the heart, considerable improvement in hemodynamics can be achieved in many patients. This is partly a result of a more organized contraction, and partly an avoidance of mitral regurgitation, which often additionally compromises the left ventricular function. Hemodynamic improvement has been shown to reduce the occurrence of fibrillation, and thus, the need for defibrillation, with concomitant savings of energy consumption and increased longevity of the implanted device.

Use of pacing electrodes in both the right and left ventricles avoids many problems associated with prior art left ventricle stimulation. And the retrograde ventricular access through the aorta and aortic valve 80 to the left ventricle 75 is achieved by a relatively simple procedure of puncturing the subclavia or the brachiocephalic artery which can be done under local anesthesia, in avoidance of a need for and risks of major surgical measures.

Moreover, placement of a defibrillation coil 77 in the left ventricle as well as a defibrillation coil 70 in the right ventricle allows defibrillation shocks to be delivered solely between these two electrodes, to considerably reduce the energy requirements of a successful shock. Even where individual parameters of thorax geometry and of the heart within the thorax may necessitate use of the two ventricular coils as a single pole and of the defibrillator case as the other pole, a substantial reduction in the energy consumption needed for defibrillation is achieved. By virtue of creating a substantially equal electric field distribution around the two ventricular electrodes and through the ventricular chambers, it is possible to implant a defibrillator having a maximum available energy output of only 15 joules to achieve successful defibrillation with adequate safety margin, even in patients with an enlarged heart. This means that the implanted device of the invention can be produced with a weight considerably less than 50 grams and

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WHAT IS CLAIMED IS:

1. An implantable medical interventional device adapted to provide therapy to a patient in whom the device is implanted to treat cardiac dysrhythmias, said device comprising function generating means for providing a plurality of functions corresponding to different levels of therapy for treatment of sensed dysrhythmias, including a pulse generator adapted for pacing the patient's heart by generating stimulating electrical pulses therefor; and a pair of thin leads coupled to said pulse generator and dimensioned for insertion respectively into the left and right ventricles of the patient's heart when said device is implanted, for application of said stimulating electrical pulses thereto, each of said leads including an electrode located on the respective lead for positioning in stimulating relation to cardiac tissue in a respective one of said ventricles and, when energized in unison by said pulse generator, to simultaneously pace said left and right ventricles.

2. The device of claim 1, wherein said lead adapted for insertion into the left ventricle includes an insulative sheath composed of a material of low thrombogenicity.

3. The device of claim 2, wherein said material of low thrombogenicity is selected from a group which includes silicone and polyurethane.

4. The device of claim 2, wherein said insulative sheath is coated at least in part with a biodegradable material to inhibit thrombus formation on the respective lead means.

5. The device of claim 4, wherein said biodegradable material coating includes at least one platelet inhibitor incorporated therein for timed release during disintegration of said coating.

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coil located thereon so as to be positioned within the right atrium of the patient's heart when said device and leads are implanted, said atrial pacing lead defibrillation coil being coupled to said shock generator for defibrillation of the atrial chambers.

13. An implantable pacemaker, comprising a pulse generator for generating stimulating pacing pulses, a right ventricular pacing lead including an electrode coupled to said pulse generator and adapted to be positioned in the right ventricle of a patient's heart for delivery of stimulating pacing pulses thereto, a left ventricular pacing lead including an electrode coupled to said pulse generator and adapted to be positioned in the left ventricle of the patient's heart for delivery of stimulating pacing pulses thereto, and means for applying selected ones of said stimulating pacing pulses timed for stimulating the ventricles simultaneously to said right and left ventricular pacing leads.

14. The pacemaker of claim 13, further comprising an atrial pacing lead including an electrode coupled to said pulse generator and adapted to be positioned in the right atrium of the patient's heart for delivery of stimulating pacing pulses thereto, and means for applying to said atrial pacing lead selected ones of said stimulating pacing pulses timed for stimulating the atria.

15. An implantable defibrillator, comprising a shock generator for generating electrical shock waveforms, a right ventricular lead including a defibrillation electrode coupled to said shock generator and adapted to be positioned in the right ventricle of a patient's heart for delivery of electrical shock waveforms thereto, a left ventricular lead including a defibrillation electrode coupled to said shock generator and adapted to be positioned in the left ventricle of the patient's heart for delivery of electrical shock waveforms thereto, and means for selectively applying said electrical shock waveforms of predetermined energy content simultaneously to said right and left ventricular defibrillation electrodes to establish a substantially homogeneous electric field distribution in the ventricles for defibrillation thereof.

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20. The device-implemented method of claim 19, wherein said device has separate right and left ventricular leads coupled thereto adapted for delivering sense signals indicative of a need for ventricular pacing to said device, and a pulse generator for delivering electrical pacing pulses simultaneously to said right and left ventricular leads.

21. The device-implemented method of claim 19, wherein said device possesses the capability to provide a plurality of functions corresponding to different therapies for treatment of dysrhythmias, and further including the steps of:

sensing ventricular fibrillation; and

responding to said sensed ventricular fibrillation by delivering an electrical shock waveform simultaneously to both ventricles of the patient's heart to establish and electric field of relatively uniform distribution and sufficient electrical energy through the ventricles for defibrillation thereof.

22. The device-implemented method of claim 21, wherein said device has separate right and left ventricular leads coupled thereto adapted for delivering sense signals indicative of ventricular fibrillation to said device, and a shock generator for delivering electrical shock waveforms simultaneously to said right and left ventricular leads.

23. The device-implemented method of claim 20, wherein said device further has a right atrial lead coupled to said pulse generator adapted for delivering sense signals indicative of a need for atrial pacing of the patient's heart to said device, and for receiving pacing pulses for atrial stimulation of the patient's heart in response to said atrial sense signals.

24. The device-implemented method of claim 21, further including the steps of:

sensing atrial fibrillation; and

responding to said sensed atrial fibrillation by delivering an electrical shock waveform between the right atrium and selectively either of the right and

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waveforms; and means adapted to deliver at least one of said therapies concurrently to both ventricles of the patient's heart.

29. A method for providing therapy to a patient from a medical interventional device to treat cardiac dysrhythmias, wherein the device performs a plurality of functions corresponding to different levels of therapy for treatment of sensed dysrhythmias, and responds to each different type of sensed dysrhythmia to generate an electrical waveform therapy among a variety of therapies appropriate to terminate the respective sensed dysrhythmia including at least electrical pulse and shock waveform therapies therefor, the method comprising the steps of implanting an electrical lead that includes an electrode for delivering at least one of said pulse and shock waveform therapies in each of the right and left ventricles of the patient's heart, and electrically connecting each lead to said device to enable said electrode thereof to receive said at least one of the therapies.

30. The method of claim 29, including, prior to implanting the lead, the step of coating at least a portion of the electrical lead to be implanted in the left ventricle with a biodegradable carrier impregnated with a thrombus inhibitor adapted to be time-released into blood in the locality of said portion of the lead in the left ventricle during disintegration of said carrier, to avoid embolization of a thrombus thereat.

31. The method of claim 30, including the step of selecting the biodegradable carrier to degrade harmlessly in the blood with negligible systemic impact, and selecting the thrombus inhibitor from a group comprising ticlopidine, aspirin, heparin, and hirudin.

32. The method of claim 31, including the step of selecting at least one physical parameter of the biodegradable carrier to fix complete disintegration thereof within a period of from about one month to about three months from the time of implanting the lead, for time-release of the thrombus inhibitor over said period.

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conductive case in which the therapy-providing means of said device are housed as the cathode.

39. The method of claim 34, including the steps of implanting an electrical lead with a pacing electrode and a defibrillating electrode thereon in the right atrium of the patient's heart, and applying said shock waveform therapy to the defibrillating electrodes of both the right atrial lead and the left ventricular lead simultaneously to terminate atrial fibrillation.

40. The method of claim 34, including the steps of detecting the local ECG at the left and right ventricles, and comparing the characteristics of size and morphology thereof for diagnosis of cardiac activity from which to discriminate ventricular and supraventricular tachycardias from one another.

41. The method of claim 39, including the step of selecting leads to be implanted in the right atrium, right ventricle, and left ventricle of the patient's heart which are covered with an insulating sheath selected from a group comprising silicone and polyurethane, and in which the sheath is coated with a material selected from a group comprising iridium oxide and titanium nitrate.

42. The method of claim 29, including the steps of implanting separate electrical leads each with a pacing electrode thereon in the right and left atria of the patient's heart, and simultaneously pacing both atria.

43. The method of claim 33, including the steps of administering a platelet inhibitor into the patient's vascular system for a limited period of time to facilitate healing and a build-up of connective tissue on electrodes of the lead implanted in the left ventricle to avoid interference with operation of the aortic valve.

44. A method for providing therapy to a patient from an implanted medical interventional device to treat cardiac dysrhythmias, comprising the steps of simultaneously stimulating the right and left ventricles of the patient's heart

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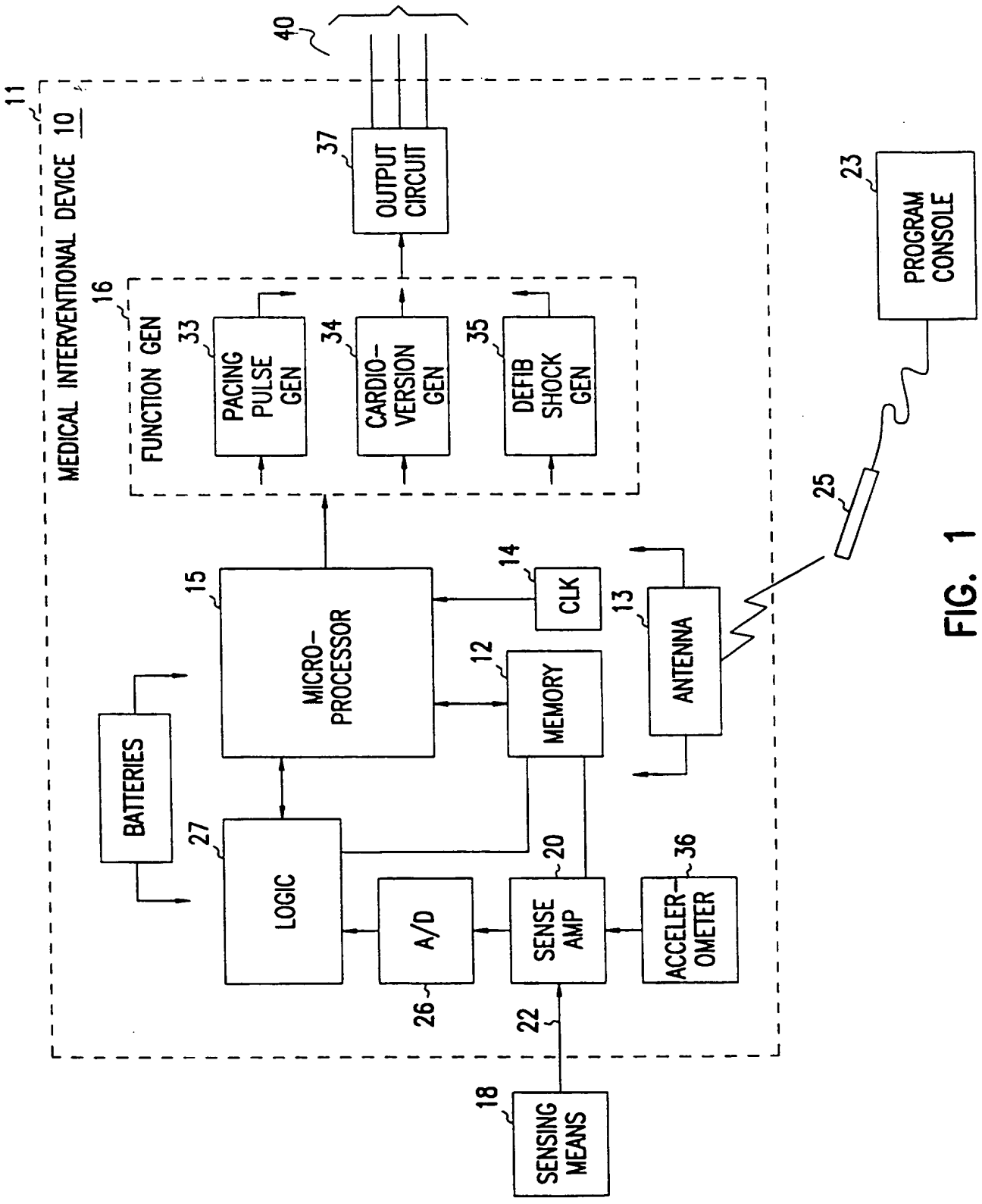

FIG. 1

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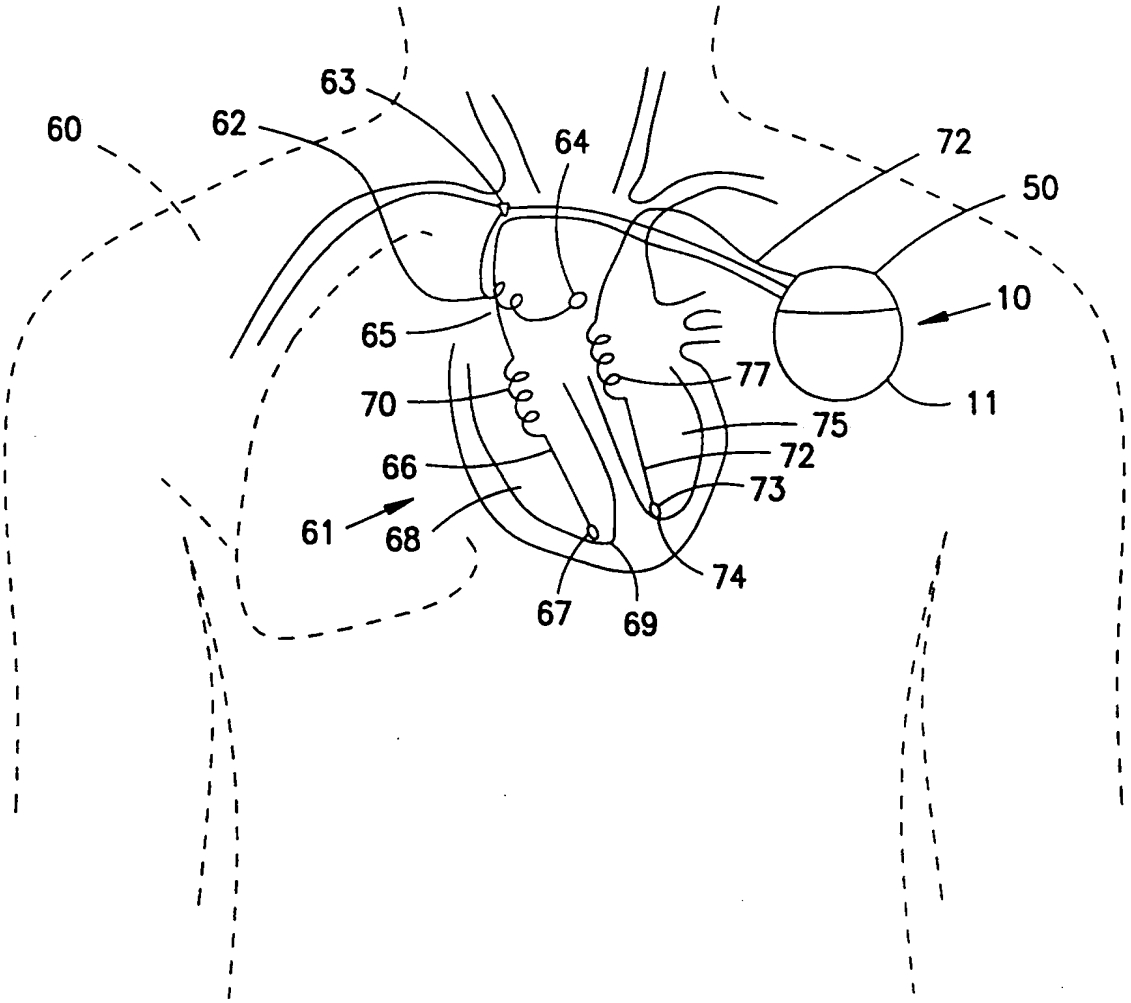

FIG. 3

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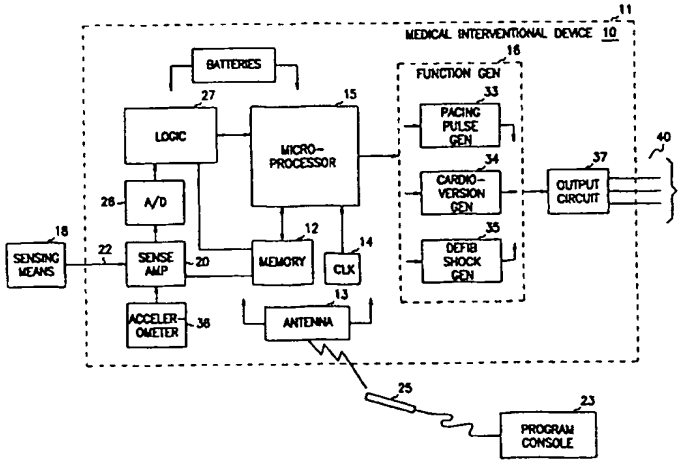

(57) Abstract

Device and method are disclosed in which leads with pacing and defibrillating electrodes are implanted into both the right and left ventricles of a patient's heart to enable simultaneous pacing of both ventricles to reduce the width of the QRS complex of the patient's cardiac activity to a more normal duration, and, when appropriate, to apply electrical shock waveforms to both ventricles simultaneously for lower energy defibrillation of the ventricles. In applying the defibrillation therapy, the defibrillating electrode in the left ventricle may be used as the anode and the defibrillating electrode in the right ventricle may be used as the cathode, or both ventricular defibrillating electrodes may be the anode and the metal case in which the shock waveform generator is implanted may be the cathode. Implanting a lead with pacing and defibrillating electrodes in the right atrium enables selective pacing and defibrillation of the atria, in which atrial fibrillation is treated by applying the shock waveform across the right atrial and left ventricular defibrillation electrodes.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US 99/16656

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/368 A61N1/39 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 4 928 688 A (MOWER MORTON M) 29 May 1990 (1990-05-29) column 5, line 16-49 ---	1,13 2,3 14,26-28
X A	US 5 540 727 A (SALO RODNEY W ET AL) 30 July 1996 (1996-07-30) column 3, line 20-42 ---	13,14 1,26-28
E A	WO 99 44682 A (MOWER MORTON M) 10 September 1999 (1999-09-10) page 5, line 9-21 page 7, line 16-18 --- -/--	15,16 1,9-13, 17,18, 26,28

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 February 2000	01 03 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Grossmann, C.

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Form PCT/ISA/210 (second sheet) (July 1992)

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/16656

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 19-25, 29-44
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internation pplication No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4928688 A	29-05-1990	NONE	
US 5540727 A	30-07-1996	NONE	
WO 9944682 A	10-09-1999	AU 2981499 A	20-09-1999
EP 0784994 A	23-07-1997	JP 9192239 A	29-07-1997
EP 0601804 A	15-06-1994	US 5509933 A	23-04-1996
		US 5477864 A	26-12-1995
		AU 5219693 A	16-06-1994
		JP 6233811 A	23-08-1995
		US 5573401 A	12-11-1996
		US 5545227 A	13-08-1996
		US 5690670 A	25-11-1997
		US 5782910 A	21-07-1998
		US 5716400 A	10-02-1998
		US 5676632 A	14-10-1997
		US 5562730 A	08-10-1996
		US 5713947 A	03-02-1998
		US 5685306 A	11-11-1997
		US 5674280 A	07-10-1997
		US 5683442 A	04-11-1997
		CA 2110779 A	08-06-1994
US 5050601 A	24-09-1991	NONE	
US 5224475 A	06-07-1993	AU 660518 B	29-06-1995
		AU 3059492 A	15-06-1993
		CA 2121795 A	27-05-1993
		EP 0618823 A	12-10-1994
		JP 6510688 T	01-12-1994
		US 5344430 A	06-09-1994
		WO 9309844 A	27-05-1993
US 5720768 A	24-02-1998	CA 2248952 A	27-11-1997
		EP 0901397 A	17-03-1999
		WO 9744090 A	27-11-1997
US 5324324 A	28-06-1994	NONE	

BNSDOCID: <WO___0004950A3_I_>